

# FOOD AND DRUG ADMINISTRATION

Center for Drug Evaluation and Research

*Advisory Committee for Reproductive Health Drugs*

*The committee will discuss biologic license applications (BLA) 125320, 125331, 125332, and 125333 for denosumab, submitted by Amgen. The proposed indications are treatment of osteoporosis in postmenopausal women, prevention of osteoporosis in postmenopausal women, treatment and prevention of bone loss in patients undergoing hormone ablation for prostate cancer, and treatment and prevention of bone loss in patients undergoing hormone ablation for breast cancer.*

## AGENDA

August 13, 2009

8:00 a.m.	Call to Order	<b>Sandra Carson, MD</b> Chair, Advisory Committee for Reproductive Health Drugs (ACRHD)
	Introduction of Committee	
	Conflict of Interest Statement	<b>Kalyani Bhatt</b> Designated Federal Official, ACRHD
8:05 a.m.	Introduction	<b>George Benson, M.D.</b> Deputy Director Division of Reproductive and Urologic Drugs (DRUP)
8:15 a.m.	<u>Sponsor Presentation</u>	
	Introduction	<b>Paul Eisenberg, MD, MPH</b> Senior Vice President Global Regulatory Affairs & Safety Amgen Inc
	Burden of Disease and Need for Improved Therapy in Postmenopausal Osteoporosis (PMO) and Hormone Ablation Therapy (HALT)	<b>Ethel Siris, MD</b> Columbia University Medical Center, New York Presbyterian Medical Center Immediate Past President, National Osteoporosis Foundation
	Discovery of RANK Ligand and Development of Denosumab	<b>David Lacey, MD</b> Senior Vice President Research Amgen Inc

	Denosumab Clinical Efficacy and Safety Assessments: PMO & HALT	<b>Catherine Stehman-Breen, MS, MD</b> Vice President Global Development Amgen Inc
	Denosumab Pharmacovigilance Plan: PMO & HALT	<b>Paul Eisenberg, MD, MPH</b> Senior Vice President Global Regulatory Affairs & Safety Amgen Inc
9:45 a.m.	Break	
10:00 a.m.	<u>FDA Presentation</u>	
	Denosumab Efficacy Analysis	<b>Vaishali Popat, MD</b> Medical Officer, DRUP
	Denosumab Safety Analysis	<b>Adrienne Rothstein, PharmD</b> Clinical Analyst, DRUP
	Bone Histomorphometry Denosumab Safety Summary Summary of Risks and Benefits of Denosumab Therapy	<b>Theresa Kehoe, MD</b> Clinical Team Leader, DRUP
11:30 a.m.	Questions to the Presenters	
12:00 p.m.	Lunch	
1:00 p.m.	Open Public Hearing	
2:00 p.m.	Questions to the Presenters	
2:30 p.m.	Questions to ACRHD	
5:00 p.m.	Adjourn	